Patient Safety:
A Framework for Excellence

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Overriding Tenet:

Medical accidents are usually the result of complex systems failure. Although incompetent and malfeasant staff exist, adverse outcomes are more commonly the result of systems problems. As safety in the aviation industry improved only after its leaders adopted this tenet, safety in medicine will not improve unless its complex systems are redesigned.

A Framework for Excellence

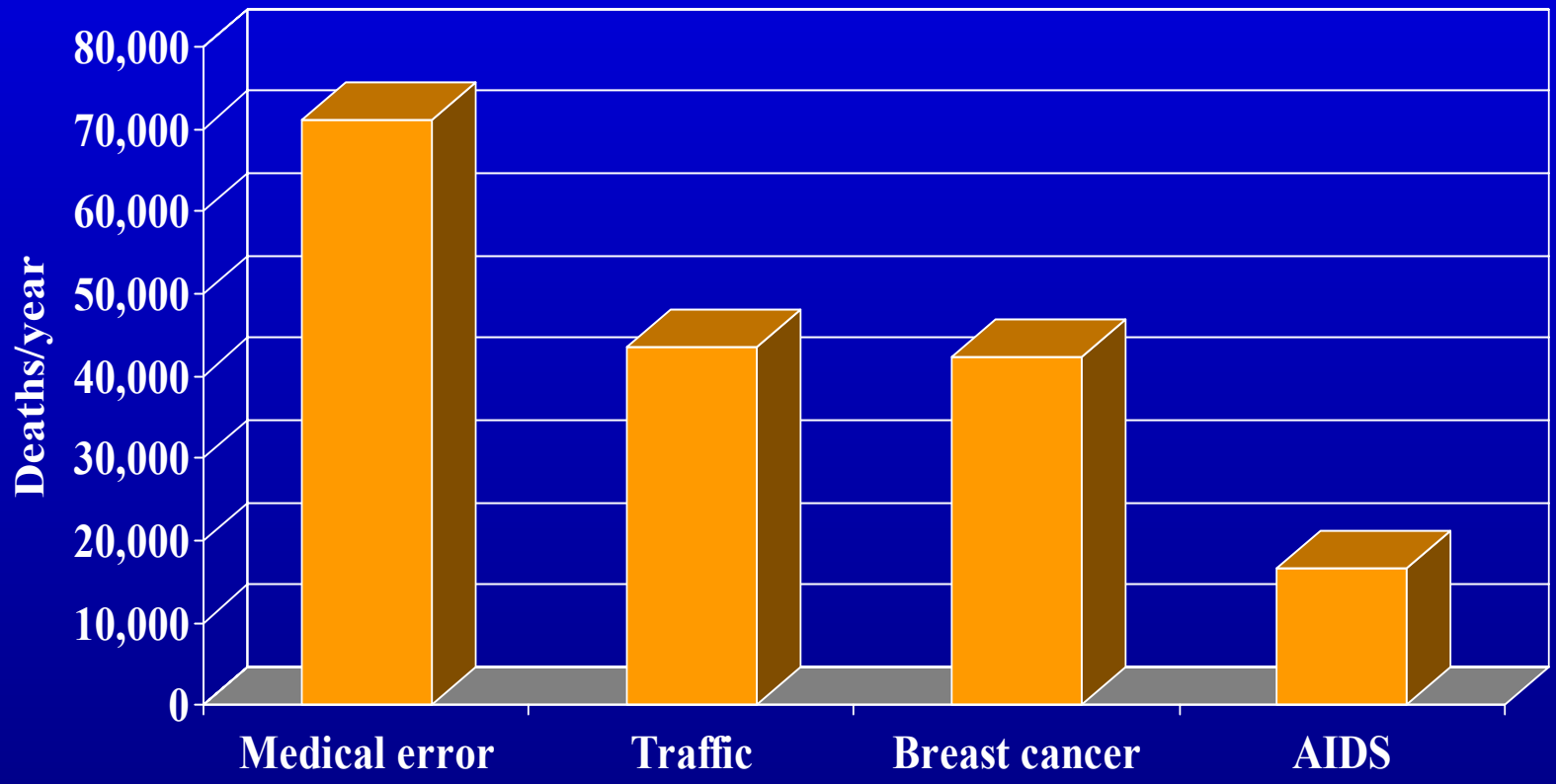
1. Accept the fact that a problem exists
2. Accept that safety is a property of the system
3. Accept the fact that we are all human
4. Make change happen

Step 1: Accept the fact that a problem exists.

IOM Report

- Rate of adverse events in hospitals:
  - Colorado/Utah study: 2.9% (8.8% fatal)
  - New York study: 3.7% (13.6% fatal)
  - Over half were preventable
- Extrapolates to 44,000 – 98,000 deaths/year
- Total national costs of preventable adverse events = $17 – 29 billion, half of which are health care costs

1999 Institute of Medicine Report



Adverse Drug Events: Facts

- 6.5 ADE/100 non-obstetrical admissions
- 5.5 potential ADE (intercepted)/100 non-ob admits
- severity:
  - fatal: 1%
  - life-threatening: 12%
  - serious: 30%
  - significant: 57%

JAMA 1995; 274:29-34

Incidence of Adverse Drug Reactions in Norway

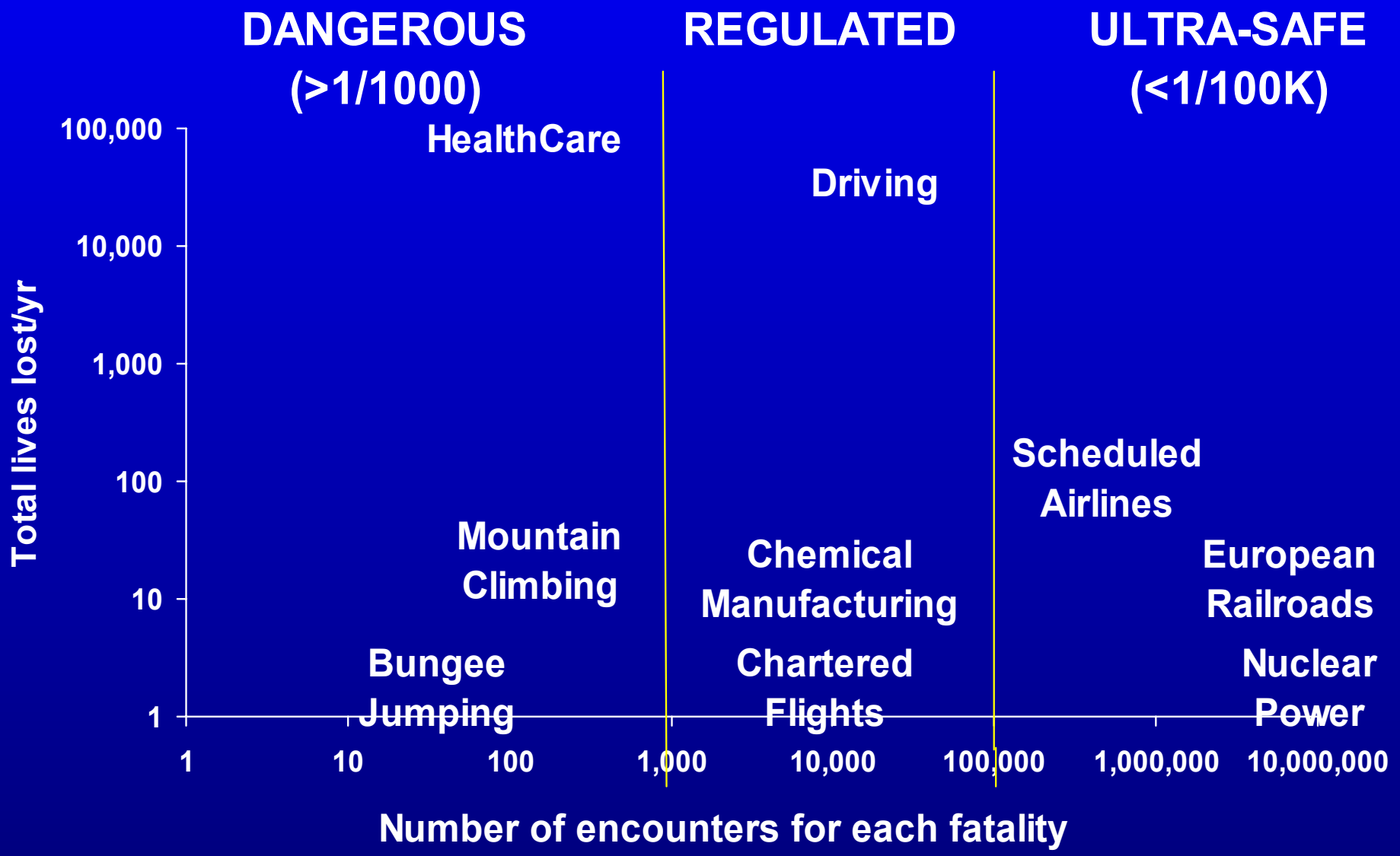
- Examined 732 deaths on internal medicine unit
- 133 (18.2%) directly or indirectly associated with drugs
- equals 9.5 deaths/1,000 admissions
- autopsy data needed to confirm ADE in > 1/2 cases
- elderly and those using more drugs more at risk

Ebbesen J, Arch Intern Med 2001; 161:2317

IHI Idealized Design of the Medication Process Trigger Study

- Uses triggers to identify potential harm
- Sample 10 charts/week
- 200 hospitals participating
- Harm rate = 25% (adult hospitals); 37% (pediatric hospitals)

How Hazardous Is Health Care?

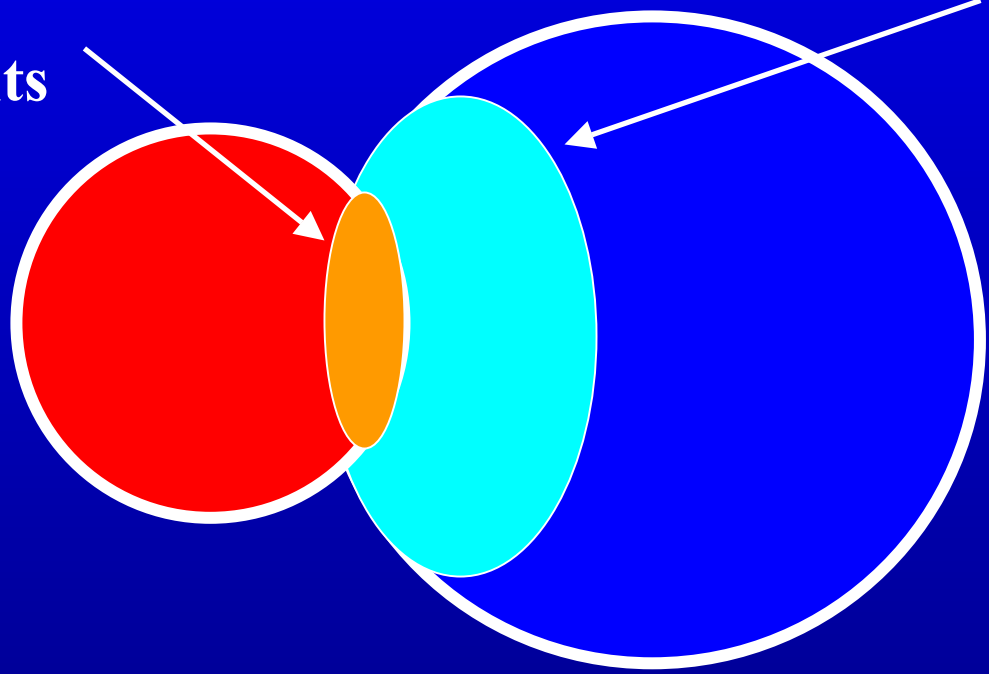


Lucian Leape, 2/2001

Harm vs. Error

Preventable Adverse Events

Potential Adverse Events



Adverse Drug Events

Medication Errors

All harm is preventable.
We just don’t know how.

Costs of Adverse Drug Events

- Length of stay increase: 1.91 days
- Hospital cost increase: $2,262/case

Classen DC et al. JAMA 1997;277:301

- Length of stay increase: 4.6 days
- Hospital cost increase: $4,685/case

Bates DW, et al. JAMA 1997;277:307

- Excludes liability costs

Costs of Adverse Drug Events
Malpractice Claims

- $64,000 - $74,200: outpatient ADE & nonpreventable inpatient ADE
- $376,500: preventable inpatient ADE

Arch Intern Med 2002;162:2414-20

The Scope of the Problem

	Physicians	General Public
Experienced error in personal or family care	35%	42%
Error caused serious health problem	18%	24%
Error caused death	7%	10%
Error caused long-term disability	6%	11%

Blendon: NEJM 12/12/2002

The Scope of the Problem

- 29% of physicians have seen a medical error that resulted in serious harm within the past 12 months
- 60% of physicians believe they would see a similar error at their institution within the next year

Blendon: NEJM 12/12/2002

Safety Awareness
How many Americans die each year from medical errors?

	Physicians (%)	Public (%)
500	17	24
5,000	46	36
50,000	25	20
100,000	9	7
> 500,000	1	4

Blendon: NEJM 12/12/2002

Step 2: Accept that safety is a property of the system and that systems are comprised of processes.

“Systems produce precisely the outcomes they are designed for.”

Don Berwick

Cerebyx

(Fosphenytoin Sodium Injection)

50 mg PE/mL

(PE = phenytoin sodium equivalents)

10 mL vial

Cerebyx

(Fosphenytoin Sodium Injection)

500mg PE in 10 mL

(PE = phenytoin sodium equivalents)

10 mL vial

Complex Systems:
Probability of Performance Error

	Probability of Error, Each Step			
# Steps	0.05	0.01	0.001	0.0001
1	0.05	0.01	0.001	0.0001
25	0.33	0.05	0.005	0.0002
50	0.92	0.39	0.05	0.005
100	0.99	0.63	0.10	0.01

If there is a better way to do something, we should all do it that way because it's better. But if there is no known best practice we should settle on 1 because the system and its players cannot execute all of those practices without an unacceptably high failure rate.

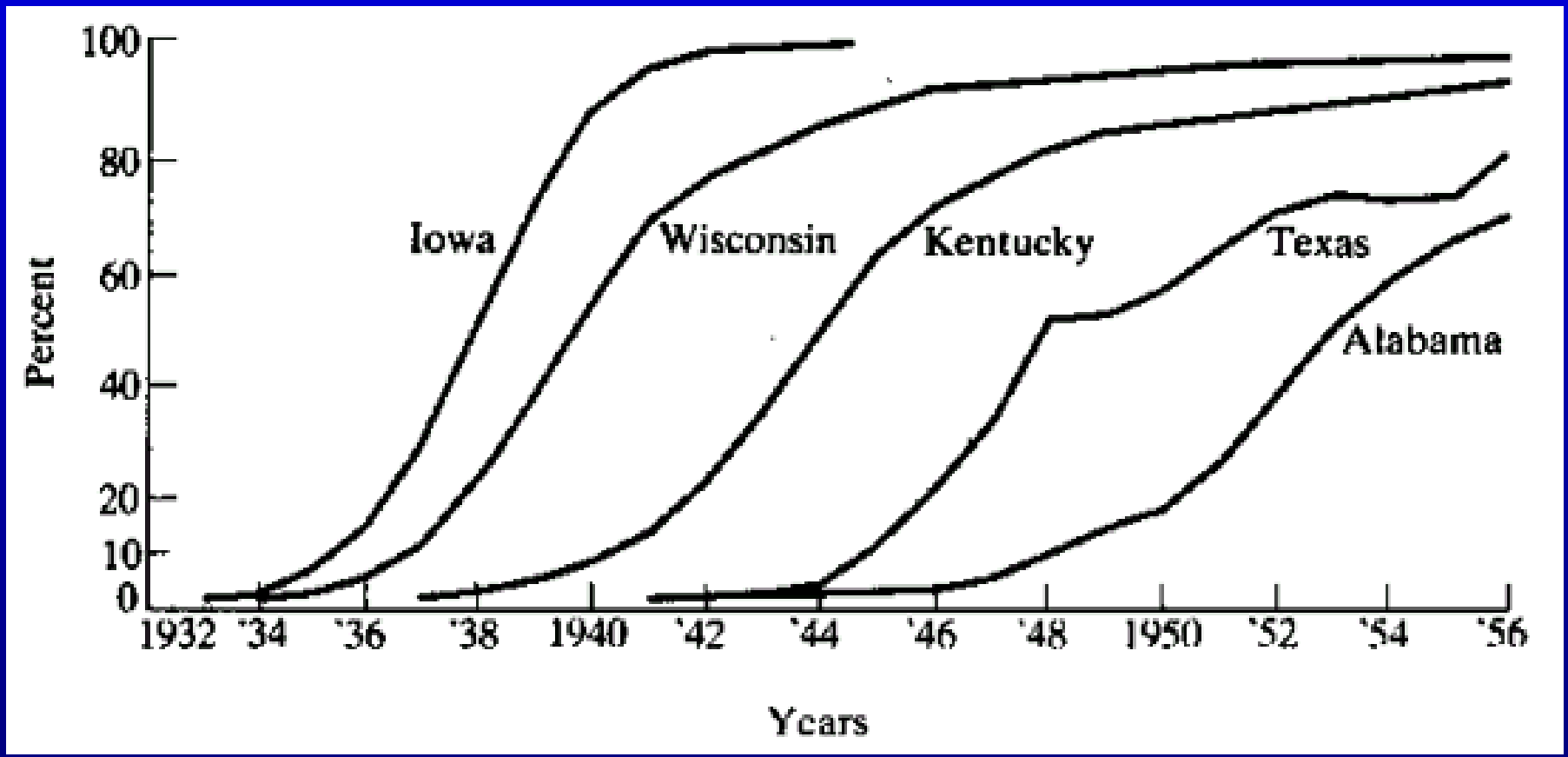
Allan Frankel

How many different:

- Sliding scale insulin protocols
- Surgeon-specific recipe or procedure cards
- Methods of marking the surgical site
- Methods of dosing warfarin
- IV pumps
- Pediatric immunization protocols
- Antibiotics for community-acquired pneumonia
- Post-op pain regimens

Diffusion of Innovations: Iowa Corn Model

Rogers, Everett. (1995). Diffusion of innovations. Fourth edition. New York, NY: The Free Press.



The average time from the publication of a definitive double-blind clinical trial to the finding's universal application is 17 years.

Only 54.9% of recommended care is received by patients.

McGlynn et al. NEJM 2003; 348:2635

Step 3. Appreciate that even health care providers are human.

Errors with ATM machines

Nominal Human Error Rates

Activity	Human error probability
Error of commission (misreading a label)	0.003
Error of omission without reminders	0.01
Error of omission when items imbedded in a procedure	0.003
Simple math error with self-checking	0.03
Monitor or inspector fails to detect error	0.1
Personnel on different shifts fail to check hardware unless required by checklist	0.1
General error in high stress when dangerous activities occurring rapidly	0.25

Salvendy G. Handbook of human factors & ergonomics 1997.

Categories of Errors

- Slips: Right intention; incorrectly executed
- Lapses: Right intention; not executed
- Mistakes: Wrong intention

Reasons for Mistakes and Slips

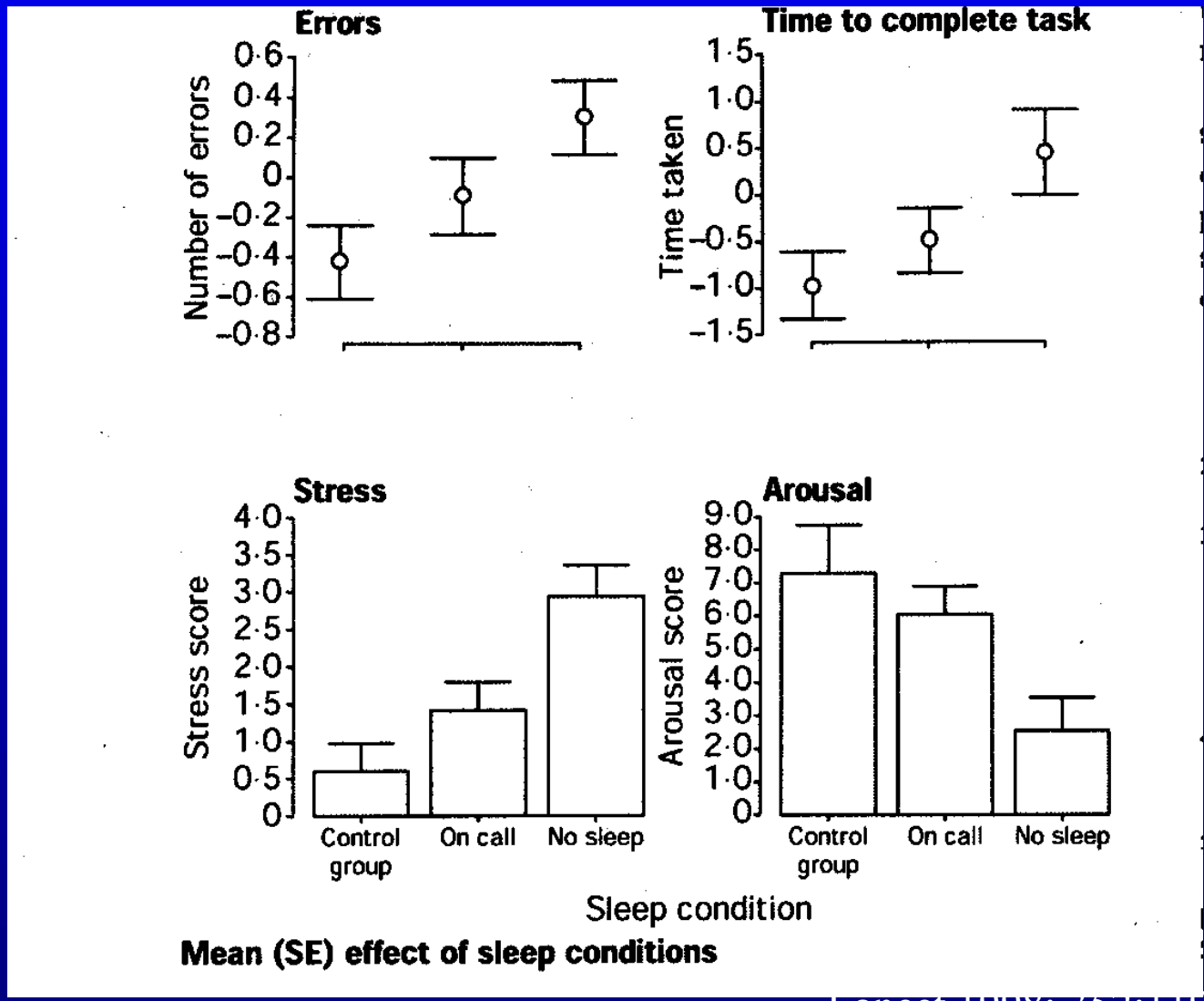
- Mistakes
  - misinterpretation
  - lack of knowledge
  - habits of thought
- Slips
  - interruptions
  - hurry
  - fatigue
  - anxiety
  - anger
  - boredom
  - fear

“Health care is the only industry that does not believe that fatigue diminishes performance.”

Lucian Leape

Being awake for 24 hours results in impairment of judgment and physical dexterity equivalent to a blood alcohol level of 0.1.

Sleep Deprivation on Surgeon's Dexterity



Mean (SE) effect of sleep conditions

Lancet 1998; 352:1191

Influence of Nurse Staffing on Outcomes

- Review of
  - 232,342 surgical patients
  - 10,184 staff nurses
  - 168 hospitals in Pennsylvania
- Adjusted for patient, nurse and hospital characteristics
- Baseline nurse:patient ratio = 4:1

Aiken et al JAMA 2002; 288:1987-93

Influence of Nurse Staffing on Outcomes

- For every additional patient/nurse:
  - Mortality risk = 1.07
  - Failure to rescue risk = 1.07
  - Job dissatisfaction = 1.15
  - Emotional exhaustion = 1.23

Aiken et al JAMA 2002; 288:1987-93

Hospitals are the only high-risk system where students are brought to bear great responsibilities and asked to play a major role.

Rene Amalberti

Human Factors Principles & Systems Design

- Avoid reliance on memory
- Simplify
- Standardize
- Use constraints and forcing functions
- Use protocols and checklists

Human Factors Principles & Systems Design

- Improve access to information
- Decrease reliance on vigilance
- Reduce hand-offs
- Increase feedback
- Decrease look-alikes
- Careful automation

Step 4: Take action and make change happen.

Preventing Errors

	Physicians	General Public
Mandated reporting	23%	71%
Public release of serious errors	14%	62%
Suspending physicians	3%	50%
Reduce work hours of residents	33%	66%

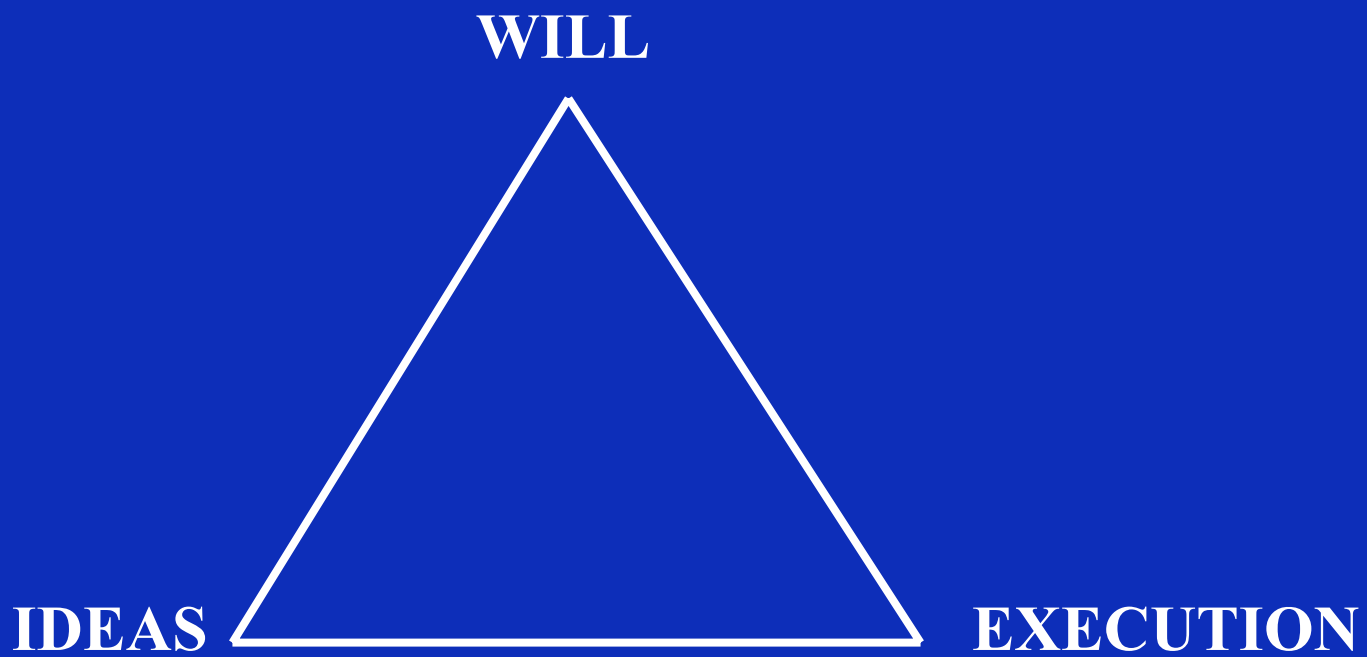
Blendon: NEJM 12/12/2002

Preventing Errors

	Physicians	General Public
High risk procedures at high volume hospitals	40%	45%
Computerized records	19%	46%
Computerized prescribing	23%	45%

Blendon: NEJM 12/12/2002

The Achievement Triangle



Culture:
The Key to Patient Safety

Culture:

- the set of shared attitudes, values, goals, and practices that characterizes a company or corporation

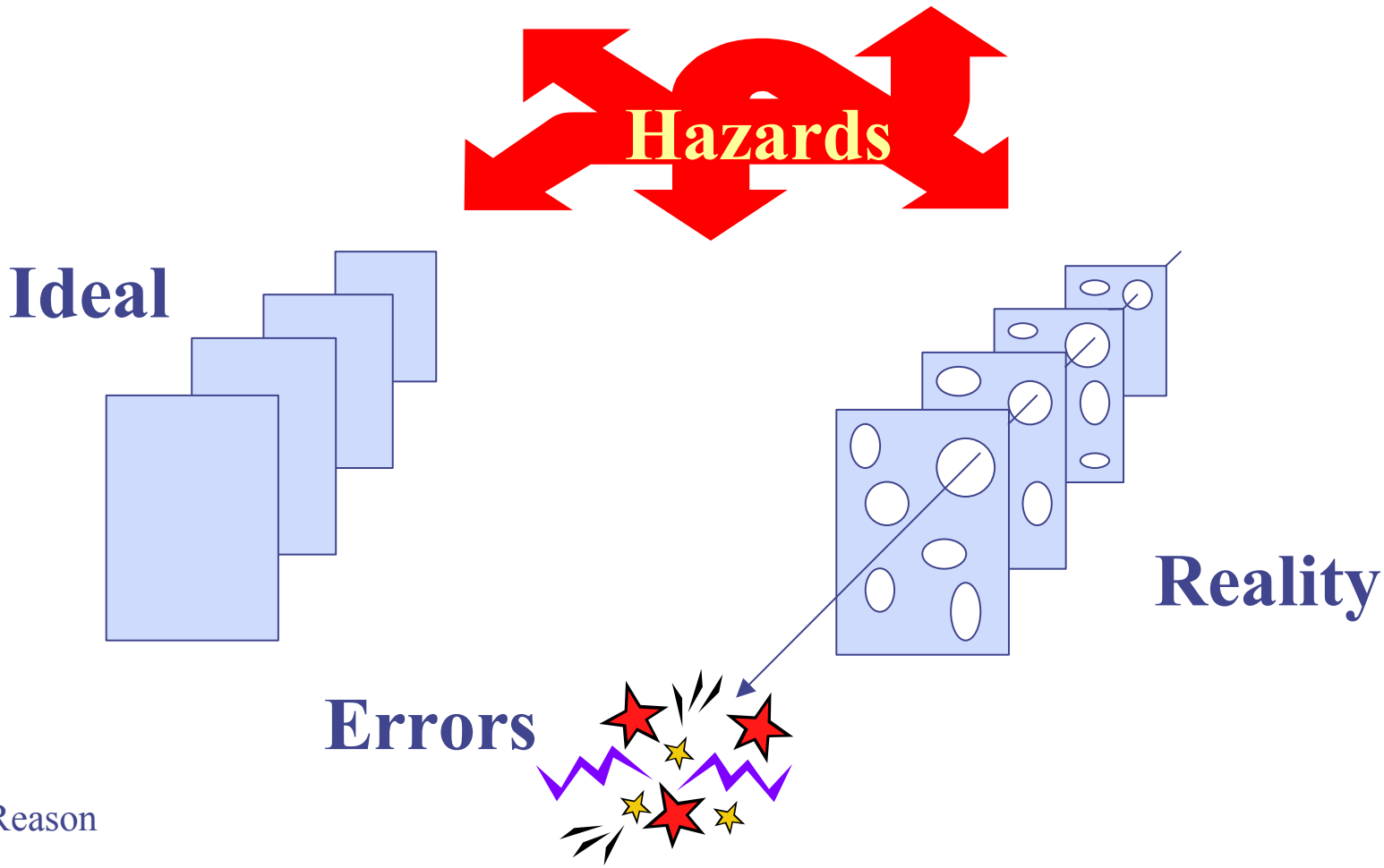
WWWebster Dictionary 1998

What you think

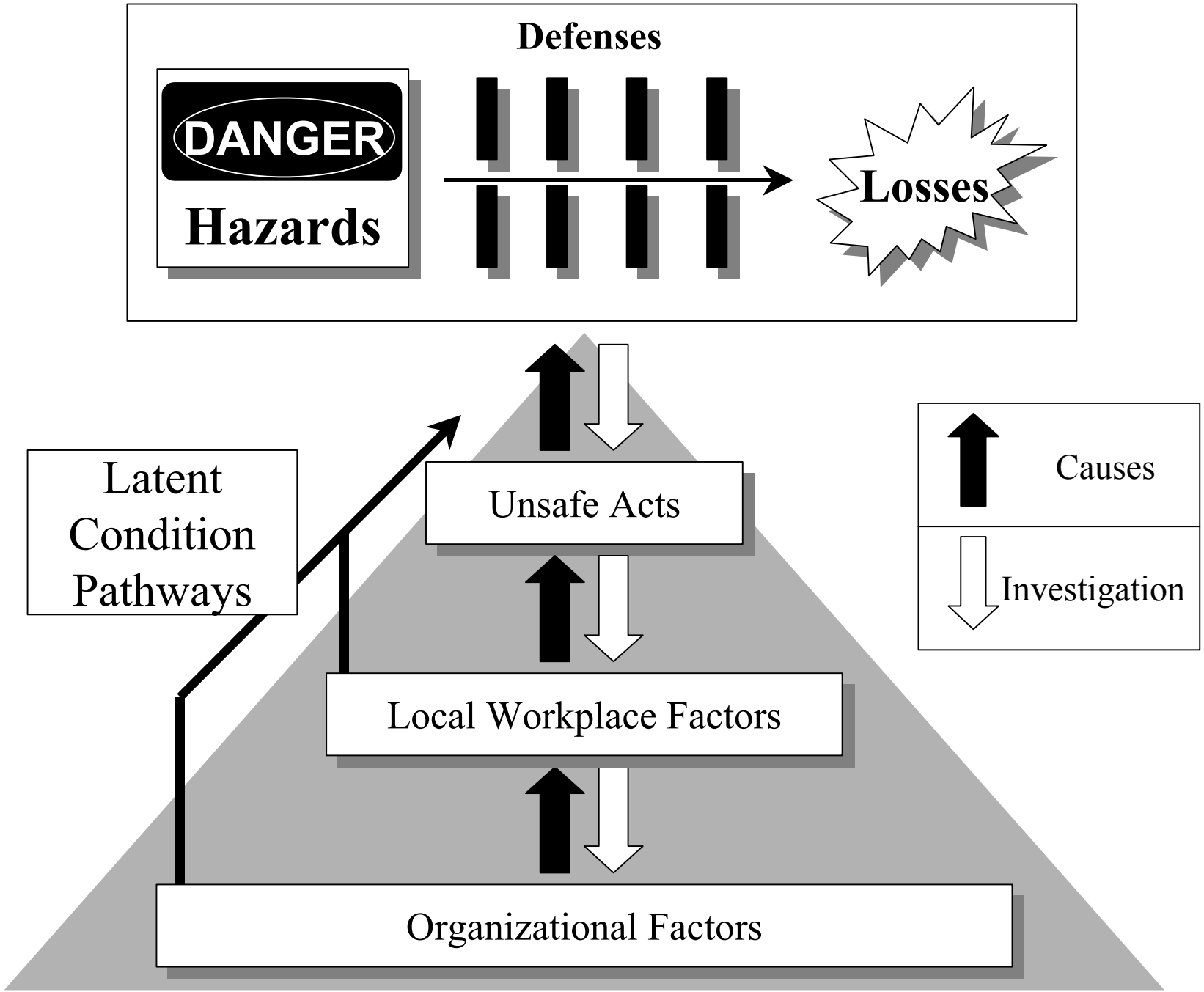
What you do

What you say

Swiss Cheese Model
Defenses Against Errors



J. Reason



Reason, J. Managing the Risks of Organizational Accidents

Teamwork & Communication

Teamwork and Conflict Resolution

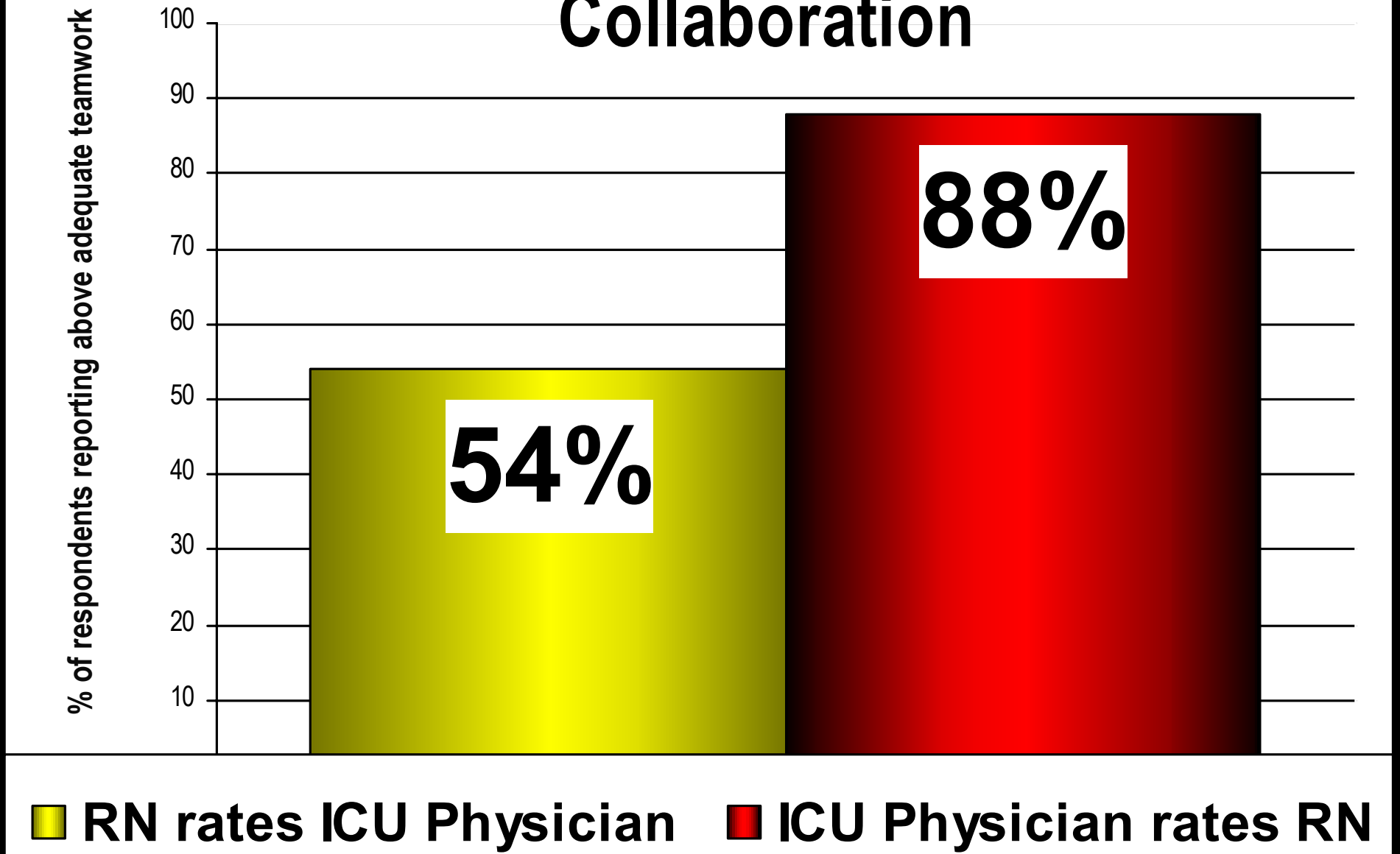
- **Conflict was observed in 10% of flights and 10% of surgeries**

- **Resolved in 80% of instances in cockpit**

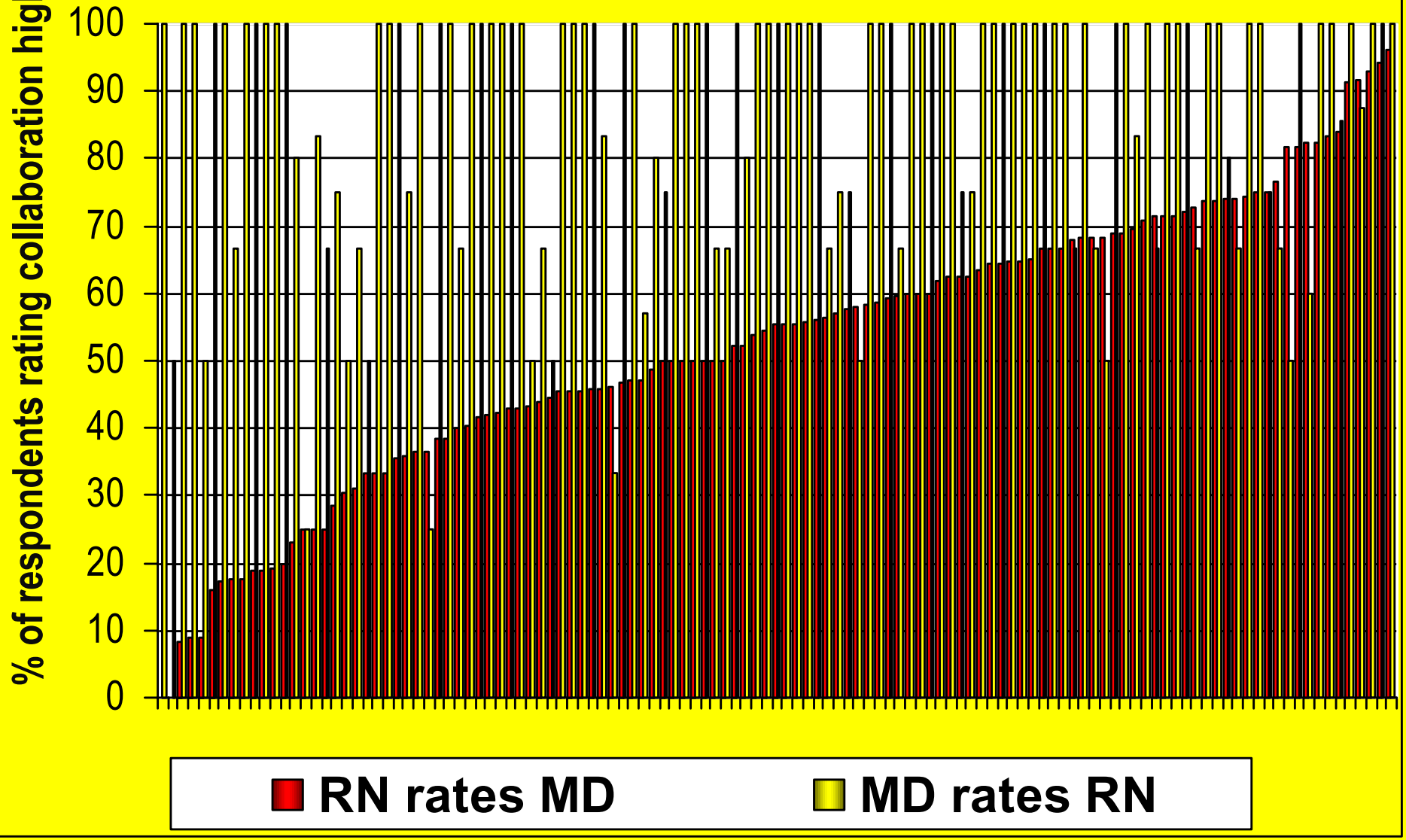
- **Resolved in 20% of instances in operating room**

ICU Teamwork Ratings: MDs and RNs rate each other

ICU Physicians and ICU RN Collaboration



Collaboration rating discrepancies between MD and RN



How Different Organizational Cultures Handle Safety Information

Pathological Culture

- Don't want to know
- Messengers (Whistle blowers) are "shot"
- Failure is punished or concealed
- New ideas are actively discouraged

Bureaucratic Culture

- May not find out
- Messengers are listened to if they arrive
- Failure leads to local repairs
- New ideas often present problems

Generative Culture

- Actively seek it
- Messengers are trained and rewarded
- Failures lead to far-reaching reforms
- New ideas are welcomed

“Knowing is not enough;
we must apply.

Willing is not enough;
we must do.”

- Goethe